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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/461,402

06/05/1995

ANDREW H. CRAGG

94-P0273US02

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54953

7590

09/07/2011

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MINNEAPOLIS, MN 55403

EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

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DELIVERY MODE

09/07/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 08/461,402	Applicant(s) CRAGG ET AL.	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 96-106 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 96-106 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/2011 has been entered.

Claim Objections

2. Claims 96, 98, 104 and 106 are objected to because of the following informalities:
- a. Claim 96: in line 13, "the distal end" should read "a distal end".
 - b. Claim 96: in line 29, "the longitudinal axis" should read "a longitudinal axis".
 - c. Claim 98: in lines 8 and 9, "the outer" and "the inner" should read "an outer" and "an inner", respectively.
 - d. Claim 104: in line 12, "the distal end" should read "a distal end".
 - e. Claim 104: in line 28, "the longitudinal axis" should read "a longitudinal axis".
 - f. Claim 104: in line 31, insert --the-- between "of" and "at least".
 - g. Claim 104: in line 32, "a proximal end" should read "the proximal end".
 - h. Claim 106: in line 26, "the longitudinal axis" should read "a longitudinal axis".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. **Claims 96-106** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 29 of claim 96, line 28 of claim 104, and line 26 of claim 106, "said stent" lacks antecedent basis and, since there are several stents (e.g. proximal stent, distal stent) already recited in the claim, it is unclear which stent is being referred to.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 96-99, 101-104, and 106** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,800,508 in view of Martin (US 5,575,817). Claim 11 of '508 claims the invention of claims 96-98, 104, and 106 substantially including a proximal stent ("endoluminal stent") having two transversely placed tapering portions ("at least one additional stent segment of frustoconical shape") and at least one distal stent ("additional stent segment having mating frustoconical shape"; see claims 9 and 10), the proximal stent having at least one distal orifice at the distal

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end of at least one of the tapering portions which when in an expanded configuration serves to receive the male engaging portion having the frustoconical configuration of the distal stent completely within the female engaging portion of the orifice (see esp. lines of claim 10). The proximal stent and the tapering portions comprise a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of the hoops being formed of a substantially complete turn of a sinuous wire having apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent, the apices of adjacent hoops juxtaposed together and at least two juxtaposed apices connected by a securing means (see claims 1 and 2). Claim 11 of '508 does not include that a cross-sectional area ("CSA") of the distal orifice when expanded is sufficiently less than that of the proximal end of the at least one distal stent when expanded within the distal orifice so as to secure together the two stents. However, claim 11 includes that the two frustoconical shapes mate together when one of them is expanded. Martin discloses a similar arrangement of two mating stents wherein one of the stents is expanded within the other in order to secure them together (col. 3, ll. 29-36). Martin teaches that a larger CSA allows for a friction fit when one of the stents expands within the other. It would have been obvious to have modified the device of claim 11 of '508 to include such a feature in order to enhance securement between the two mating segments. Therefore, claim 11 of '508 in view of Martin '508 anticipates claims 96, 104, and 106 of the instant application.

6. Regarding claims 97 and 98, although claim 11 of '508 uses different designations for the different portions of the bifurcated stent assembly, it is clear from claim 11 that the distal stent has a proximal end which when expanded will at least partially secure with the short extension forming one of the tapered portions.

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7. Regarding claim 99, see platinum wire (12) of Martin. It would have been obvious to have added a similar wire to the device of claim 11 of '508 in order to facilitate viewing of the device.

8. Regarding claims 101 and 102, claim 11 of '508 includes that the stent assembly is used to treat a bifurcated artery but does not expressly disclose that the proximal stent defines two lumens, at least one of which is configured to be disposed entirely within the vessel and is adapted to secure to the distal stent configured to extend into one of the two branched vessels. However, Martin teaches that such a placement of a bifurcated stent assembly is known in order to ensure that blood flows in an uninterrupted manner between the main vessel and the branching vessels (see figs. 1-4). It would have been obvious to one skilled in the art to have modified the device of claim 11 of '508 to have the capability of such placement as taught by Martin in order to facilitate blood flow at a bifurcation. As to claim 102, as discussed above in more detail, claim 11 of '508 includes frustoconical mating sections.

9. Regarding claim 103, claim 11 of '508 does not include a fabric layer on any of the stents. However, Martin teaches including a fabric layer over a bifurcated stent assembly in order to treat aneurysms at a bifurcation. In particular, providing a fabric layer isolates the blood flow from the walls of the compromised blood vessel. It would have been obvious to one skilled in the art to have added a fabric layer to the device of claim 11 of '508 in order the vessel wall from blood flowing through the stent assembly thereby allowing treatment of an aneurysm.

10. **Claim 100** is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,800,508 in view of Martin as applied to claim 96 above and further in view of Liebig (US 3,805,301). Claim 11 of '508 is silent on the claimed radiographic indicia. Liebig teaches that it is well known to provide markers along the longitudinal axis of a stent such that the rotational orientation affects the shape of the marker

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(see abstract). In particular, if the graft is twisted at all, the marker will be twisted. It would have been obvious to provide radiographic indicia in the form of a wire attached in a longitudinal manner as taught by Liebig on the device of claim 11 of '508 so that any twisting of the stent structure can be easily determined by viewing the marker. With this modification, the radiographic image of the radiographic indicia varies with rotational orientation of the stent.

11. **Claim 105** is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,800,508 in view of Martin as applied to claim 96 above and further in view of Chuter (US 5,562,726). Claim 11 of '508 in view of Martin discloses the invention substantially including the addition of a fabric material to the stents as taught by Martin but does not disclose securing the proximal and distal stents with suture. However, Chuter discloses that it is well known to use suture to attach distal graft legs to a bifurcated proximal graft (see figs. 28 and 29). It would have been obvious to one skilled in the art to have further modified the device of claim 11 of '508 to include securing the proximal and distal stents with suture as taught by Chuter to provide additional means of preventing the stents and graft material from separating.

12. **Claims 96-98, 104, and 106** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,942,919 in view of Hillstead (US 4,856,516) and Cottone, Jr. (US 5,549,663; "Cottone"). Claim 7 of '919 claims the invention of claims 96-98, 104, and 106 substantially including a proximal stent having two transversely placed tapering portions and at least one distal stent, the proximal stent having at least one distal orifice at the distal end of at least one of the tapering portions which when in an expanded configuration serves to receive the male engaging portion having the frustoconical configuration of the distal stent within the female engaging portion of the orifice. A cross-sectional area ("CSA") of the distal orifice when expanded is sufficiently less than that of the

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proximal end of the at least one distal stent when expanded within the distal orifice so as to secure together the two stents. Claim 7 of '919 discloses that the stents comprise a fabric layer and wire skeletons of an expandable stent but fails to disclose that the stents comprise a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of the hoops being formed of a substantially complete turn of a sinuous wire having apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent, the apices of adjacent hoops juxtaposed together and at least two juxtaposed apices connected by a securing means (see claims 1 and 2).

13. However, Hillstead teaches constructing a stent such that it comprises a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of the hoops being formed by a substantially complete turn of a sinuous wire having apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent. It would have been obvious to incorporate this stent structure into the stents of claim 7 of '919 in order to gain the advantages associated with this structure including a high degree of flexibility and a more direct and uniform application of expansion forces to the stent (see entire document of Hillstead, esp. col. 2, ll. 14-25). Hillstead fails to disclose that the apices of adjacent hoops are juxtaposed to one another and at least two juxtaposed apices are connected by a securing means. Cottone teaches providing wire hoops which are out of phase such that apices of adjacent hoops are juxtaposed to one another and are connected by a securing means (weld point 18). These securing means are advantageous because, when applied at least to end portions of the stent, they provide anchoring portions within the stent which possess greater hoop strength than un-welded end portions, thereby making less likely unintentional movement of the stent after deployment (col. 1, ll. 20-24; col. 4, ll. 48-64). It would have been

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obvious to incorporate such a securing means as taught by Cottone into the device of claim 7 of '919 in view of Hillstead so that it too may have this advantage.

14. Regarding claims 97 and 98, see claim 7 of '919.

15. **Claims 99 and 101-103** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,942,919 in view of Hillstead and Cottone, Jr. as applied to claim 96 above and further in view of Martin (US 5,575,817). Regarding claim 99, claim 7 of '919 fails to disclose a portion of different radiopacity. Martin teaches another bifurcated stent assembly and further teaches including a platinum wire (12) in order to increase radiopacity. It would have been obvious to have added a similar wire to the device of claim 7 of '919 in order to facilitate viewing of the device.

16. Regarding claims 101 and 102, claim 7 of '919 includes that the proximal prosthesis forms a bifurcated prosthesis but does not expressly disclose that the proximal stent defines two lumens, at least one of which is configured to be disposed entirely within the vessel and is adapted to secure to the distal stent configured to extend into one of the two branched vessels. However, Martin teaches that such a placement of a bifurcated stent assembly is known in order to ensure that blood flows in an uninterrupted manner between the main vessel and the branching vessels (see figs. 1-4). It would have been obvious to one skilled in the art to have modified the device of claim 7 of '919 to have the capability of such placement as taught by Martin in order to facilitate blood flow at a bifurcation. As to claim 102, as discussed above in more detail, claim 7 of '919 includes frustoconical mating sections.

17. Regarding claim 103, claim 7 of '919 includes that the stents have a fabric layer over the stent structure.

18. **Claim 100** is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,942,919 in view of Hillstead and

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Cottone, Jr. as applied to claim 96 above and further in view of Liebig (US 3,805,301). Claim 7 of '919 is silent on the claimed radiographic indicia. Liebig teaches that it is well known to provide markers along the longitudinal axis of a stent such that the rotational orientation affects the shape of the marker (see abstract). In particular, if the graft is twisted at all, the marker will be twisted. It would have been obvious to provide radiographic indicia in the form of a wire attached in a longitudinal manner as taught by Liebig on the device of claim 7 of '919 so that any twisting of the stent structure can be easily determined by viewing the marker. With this modification, the radiographic image of the radiographic indicia varies with rotational orientation of the stent.

19. **Claim 105** is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,942,919 in view of Hillstead and Cottone, Jr. as applied to claim 96 above and further in view of Chuter (US 5,562,726). Claim 7 of '919 in view of Hillstead and Cottone discloses the invention substantially but does not disclose securing the proximal and distal stents with suture. However, Chuter discloses that it is well known to use suture to attach distal graft legs to a bifurcated proximal graft (see figs. 28 and 29). It would have been obvious to one skilled in the art to have further modified the device of claim 7 of '919 to include securing the proximal and distal stents with suture as taught by Chuter to provide additional means of preventing the stents and graft material from separating.

20. **Claims 96-99, 101-104, and 106** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 08/312,881 in view of Cottone, Jr. (US 5,549,663) and Martin (US 5,575,817). Claim 1 of '881 claims the invention of instant claim 96 substantially including a bifurcated stent assembly comprising a proximal stent and a distal stent wherein the proximal stent and distal stent are joined together by frustoconically shaped engaging male and female

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portions. Claim 1 of '881 also includes that the stents are formed by wire hoops which are perpendicular to the longitudinal axis of the stent. Claim 1 of '881 fails to disclose that the wire is sinuous with adjacent apices juxtaposed and connected by a securing means. Cottone teaches providing wire hoops which are out of phase such that apices of adjacent hoops are juxtaposed to one another and are connected by a securing means (weld point 18). These securing means are advantageous because, when applied at least to end portions of the stent, they provide anchoring portions within the stent which possess greater hoop strength than un-welded end portions, thereby making less likely unintentional movement of the stent after deployment (col. 1, ll. 20-24; col. 4, ll. 48-64). It would have been obvious to have used a sinuous wire with a securing means as taught by Cottone into the device of claim 1 of '881 so that it too may have this advantage. Claim 1 of '881 also does not include that a cross-sectional area ("CSA") of the distal orifice of the proximal stent when expanded is sufficiently less than that of the proximal end of the at least one distal stent when expanded within the distal orifice so as to secure together the two stents. Martin discloses a similar arrangement of two mating stents wherein one of the stents is expanded within the other in order to secure them together (col. 3, ll. 29-36). Martin teaches that a larger CSA allows for a friction fit when one of the stents expands within the other. It would have been obvious to have modified the device of claim 1 of '881 to include such a feature in order to enhance securement between the two mating segments. This is a provisional obviousness-type double patenting rejection.

21. Regarding claims 97 and 98, although claim 1 of '881 uses different designations for the different portions of the bifurcated stent assembly, it is clear from claim 1 that the distal stent has a proximal end which when expanded will at least partially secure with the short extension forming one of the tapered portions.

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22. Regarding claim 99, see platinum wire (12) of Martin. It would have been obvious to have added a similar wire to the device of claim 1 of '881 in order to facilitate viewing of the device.

23. Regarding claims 101 and 102, claim 1 of '881 includes that the intermediate stent portion extends distally relative to the assembly bifurcation and is adapted to be joined to a second stent which allows blood to flow from the proximal portion into the other branched vessel.

24. Regarding claim 103, claim 1 of '881 does not include a fabric layer on any of the stents. However, Martin teaches including a fabric layer over a bifurcated stent assembly in order to treat aneurysms at a bifurcation. In particular, providing a fabric layer isolates the blood flow from the walls of the compromised blood vessel. It would have been obvious to one skilled in the art to have added a fabric layer to the device of claim 1 of '881 in order the vessel wall from blood flowing through the stent assembly thereby allowing treatment of an aneurysm.

25. **Claim 100** is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 08/312,881 in view of Martin and Cottone as applied to claim 96 above and further in view of Liebig (US 3,805,301). Claim 1 of '881 is silent on the claimed radiographic indicia. Liebig teaches that it is well known to provide markers along the longitudinal axis of a stent such that the rotational orientation affects the shape of the marker (see abstract). In particular, if the graft is twisted at all, the marker will be twisted. It would have been obvious to provide radiographic indicia in the form of a wire attached in a longitudinal manner as taught by Liebig on the device of claim 1 of '881 so that any twisting of the stent structure can be easily determined by viewing the marker. With this modification, the radiographic image of the radiographic indicia varies with rotational orientation of the stent.

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26. **Claim 105** is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 08/312,881 in view of Martin and Cottone as applied to claim 96 above and further in view of Chuter (US 5,562,726). Claim 1 of '881 in view of Martin and Cottone discloses the invention substantially including the addition of a fabric material to the stents as taught by Martin but does not disclose securing the proximal and distal stents with suture. However, Chuter discloses that it is well known to use suture to attach distal graft legs to a bifurcated proximal graft (see figs. 28 and 29). It would have been obvious to one skilled in the art to have further modified the device of claim 1 of '881 to include securing the proximal and distal stents with suture as taught by Chuter to provide additional means of preventing the stents and graft material from separating.

Response to Arguments

27. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 9/2/2011
/Kathleen Sonnett/
Primary Examiner, Art Unit 3731